



#12
PATENT
Docket No. GZ 2063.10
GZ Ref. GAO 152USD1

CERTIFICATE OF MAILING

I hereby certify that this paper or fee is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231 on this date listed below.

Dated: July 31, 2002

Mary R. Zimmerman
Mary R. Zimmerman

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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In re Application for:

Charles A. NICOLETTE

Serial No.: 09/920,480

Filing Date: August 1, 2001

For: MELANOMA ANTIGENIC PEPTIDES

Examiner: Not Yet Assigned

Group Art Unit: 1644

Commissioner for Patents
Washington, D.C. 20231

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with 37 C.F.R. § 1.56, the references listed on the attached forms PTO-1449a and PTO-1449b are being brought to the attention of the Examiner for consideration in connection with the examination of the above-identified patent application. The Examiner is requested to make these documents of record.

I. Timing of the Information Disclosure Statement

This Information Disclosure Statement is submitted:

- ☐ With the new patent application submitted herewith (37 C.F.R. § 1.97(a)).
- ☐ Within three months of the application filing date or before receipt of a first Office Action on the merits; accordingly, no fee or separate requirements are required.

- ☒ Before the mailing date of the first Office Action on the merits. In the event, however that an Office Action has crossed in the mail with this Information Disclosure Statement, the Commissioner is hereby authorized to charge Deposit Account No. 50-1189 for any fees required pursuant to 37 C.F.R. §§ 1.17(p) or 1.17(i)(1).
- ☐ After receipt of a first Office Action on the merits but before a final Office Action or Notice of Allowance. A fee is required. The Commissioner is hereby authorized to charge Deposit Account No. 50-1189 for any fees required pursuant to 37 C.F.R. §§ 1.17(p) or 1.17(i)(1).
- ☐ After receipt of a final Office Action or Notice of Allowance, but before payment of the issue fee. Accordingly, a Certification under 37 C.F.R. § 1.97(e) is provided herein. The Commissioner is hereby authorized to charge Deposit Account No. 50-1189 for any fees required pursuant to 37 C.F.R. §§ 1.17(p) or 1.17(i)(1).

The undersigned certifies that:

- ☐ Each item of information contained in the Information Disclosure Statement was first cited in any communication mailed from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement.
- ☐ No item of information contained in this information disclosure statement was cited in a communication mailed from a foreign patent office in a counterpart foreign application or, to the knowledge of the undersigned after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

II. Copies of the Cited Items:

- ☐ Copies of all of the items listed on the attached Form PTO-1449 are enclosed.
- ☐ Copies of only the following items listed on the attached Form PTO-1449 are enclosed: _____
- ☒ Copies of those items which are marked with an asterisk (*) in the attached Forms PTO-1449a and 1449b are not supplied because they were previously cited by or submitted to the Patent Office in a prior Application

No. 09/249,272, filed February 11, 1999, now U.S. Patent No. 6,306,640 issued October 23, 2001, and relied upon in this application for an earlier filing date under 35 U.S.C § 120. See 37 C.F.R. § 1.98(d).

- ☐ Copies of those items which are marked with an asterisk (**) in the attached Form PTO-1499 were cited in a foreign examination report in a related case. A copy of the search report and the cited references not already of record in this application are attached hereto.

III. Concise Explanation of Relevance:

- ☒ A concise explanation of relevance of the items listed on Form PTO-1449 is not given.
- ☐ A concise explanation of relevance of [some of] the items listed on Form PTO-1449 is in the form of an English language copy of a Search Report from a foreign patent office, issued in a counterpart application, which refers to the relevant portions of the references (copy attached).

IV. Conclusion:

Citation of the above documents shall not be construed as:

1. an admission that the documents are necessarily prior art with respect to the instant invention;
2. a representation that a search has been made, other than as described above; or
3. an admission that the information cited herein is, or is considered to be, material to patentability as defined in § 1.56(b).

It is respectfully requested that the Examiner indicate consideration of the cited references by returning a copy of the attached form PTO 1449 with initials or other appropriate marks.

Applicant would take this opportunity to bring to the Office's attention related U.S. patent application serial numbers 09/812,238 and 09/862,260 filed March 19, 2001 and May 21, 2001, respectively.

The Commissioner is hereby authorized to charge Deposit Account No. 50-1189, **Attorney Billing Ref. 19442-7229** for any additional fees required in connection with the filing of this Information Disclosure Statement.

Respectfully submitted,

Dated:

July 31, 2002

By:

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GP 1644

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Substitute for form 449A-PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1 of 1

Complete if Known

Application Number	09/920,480
Filing Date	August 1, 2001
First Named Inventor	Charles A NICOLETTE
Art Unit	1644
Examiner Name	Not Yet Assigned
Attorney Docket Number	GZ 2063.10

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number Number – Kind Code ² (if known)	Publication Date MM-DD-YY	Name of Patentee or Application of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1	US-5,695,937	12/9/97	Kinzler et al.	
	2	US-5,869,445	2/9/99	Cheever, et al.	
	3	US-6,028,059	2/22/00	Curiel, et al.	
	4	US-5,844,075 (*)	12/1/98	Kawakami et al.	

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FOREIGN PATENT DOCUMENTS

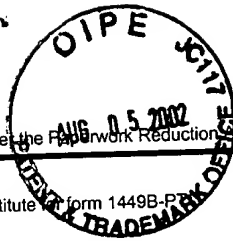
Examiner Initials*	Cite No. ¹	Foreign Patent Document Country Code ³ – Number ⁴ – Kind Code ⁵ (if known)	Publication Date MM-DD-YY	Name of Patentee or Application of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
	5	FR 2,757,169		Institute Nat'l de la Sante et de la Recherche Medical Inserm Establis Public a Caract Scient et Tech		
	6	WO 99/02183		CTL Immunotherapies Corp.		
	7	WO 00/20457		Genzyme Corp.		
	8	WO 97/35035 (*)		Genzyme Corp.		

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SignatureDate
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* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

† Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, D.C. 20231.



PTO/SB/08B (10-01)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B-P

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1 of 2

Complete if Known

Application Number	09/920,480
Filing Date	August 1, 2001
First Named Inventor	Charles A. NICOLETTE
Art Unit	1644
Examiner Name	Not Yet Assigned
Attorney Docket Number	GZ 2063.10

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher city and/or country where published	T²
	1	ALEXANDER-MILLER et al. "Selective expansion of high-or low-avidity cytotoxic T lymphocytes and efficacy for adoptive immunotherapy" <i>PNAS USA</i> (1996) 93(9) :4102-4107 (*)	
	2	BLOOM et al. "Identification of tyrosine-related protein 2 as a tumor rejection antigen for the B16 melanoma" <i>J. Exp. Med</i> (1997). 185(3) :453 (*)	
	3	BORCHARDT et al., "Small molecule-dependent genetic selection in stochastic nanodroplets as a means of detecting protein-ligand interactions on a large scale" <i>Chem. Biol.</i> (1997) 4(12) :961-968 (*)	
	4	BOUCHARD et al., "Molecular characterization of a human tyrosinase-related-protein-2 cDNA. Patterns of expression in melanocytic cells" <i>Eur. J. Biochem</i> (1994). 219(1-2) :127-134 (*)	
	5	COCKLE, S.M., et al. "Thyrotrophin-releasing hormone-related polypeptides in rabbit prostate and semen are different from those in rabbit hypothalamus" <i>J. Endocrinology</i> (1989) 120 : 31-36	
	6	COLACO "Why are dendritic cells central to cancer immunotherapy?" <i>Mol. Med.</i> (January 1999) Today :14-17 (*)	
	7	FISK, B. et al. "Changes in an HER-2 peptide upregulating HLA-A2 expression affect both conformational epitopes and CTL recognition: Implications for Optimization of antigen presentation and tumor-specific CTL induction" <i>Immunol.</i> (1996) 18(4) :197-209	
	8	FORBES, J.F. "The incidence of breast cancer: The global burden, public health considerations" <i>Seminars in Oncology</i> (1997) 24(1) , Suppl. 1. pp. S1-20-S1-35	
	9	GISH et al., "Identification of protein coding regions by database similarity search" <i>Nature Genetics</i> (1993) 3 :266-273 (*)	
	10	GREENLEE, R.T. et al. "Cancer Statistics, 2001" . <i>CA Cancer J Clin</i> (2001) 51(1) :15-36	
	11	KAWAKAMI et al., "Identification of a human melanoma antigen recognized by tumor-infiltrating lymphocytes associated with <i>in vivo</i> tumor rejection" <i>PNAS USA</i> (1994) 91 :6458-6462 (*)	
	12	KAWAKAMI, Y. et al., "Cloning of the gene coding for a shared human melanoma antigen recognized by autologous T cells infiltrating into tumor" <i>PNAS USA</i> (1994) 91(9) :3515-3519 (*)	
	13	KUHNS, J.J. et al. "Poor Binding of a HER-2/neu Eptope (GP2) to HLA-A2.1 is due to a lack of interactions with the center of the peptide" <i>J. Biol. Chem.</i> (1999) 274 :36422-36427	
	14	LINDAUER et al., "The molecular basis of cancer immunotherapy by cytotoxic T lymphocytes" <i>J. Mol. Med.</i> (1998) 76 :32-47 (*)	
	15	LOCKHART, D.J. and E.A. WINZELER "Genomics, gene expression and DNA arrays" <i>Nature</i> (2000) 405 :827-836	
	16	RIES, L.A. et al. "The annual report to the nation on the status of cancer, 1973-1997, with a special section on colorectal cancer" <i>Cancer</i> (2000) 88(10) :2398-2424	
	17	RONGEUN, Y. et al. "Identification of new HER2/neu-derived peptide epitopes that can elicit specific CTL against autologous and allogeneic carcinomas and melanomas" <i>J. Immunol.</i> (1999) 163 :1037-1044	
	18	ROSENBERG et al., "Immunologic and therapeutic evaluation of a synthetic peptide vaccine for the treatment of patients with metastatic melanoma" <i>Nature Med.</i> (1998) 4(3) :321-327 (*)	
	19	SALGALLER et al., "Recognition of multiple epitopes in the human melanoma antigen gp100 by peripheral blood lymphocytes stimulated <i>in vitro</i> with synthetic peptides" <i>Cancer Res.</i> (1995) 55 :4972-4979 (*)	
	20	SCHENA et al., "Parallel human genome analysis: Microarray-based expression monitoring of 1000 genes" <i>PNAS USA</i> (1996) 93 :10614-10619 (*)	

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OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

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Signature**

Date
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¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

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